



SMOKE-FREE
THE CONSUMER ADVOCATES FOR SMOKE-FREE ALTERNATIVES ASSOCIATION

CASAA Testimony FDA TPSAC Public Hearing

Dissolvable Tobacco Products-II

March 1, 2012

Dissolvables: TPSAC DRAFT Report

Elaine D. Keller, MEd, President



45 Pack Years

- Loud nighttime wheezing
- “Productive” morning cough
- Laughing triggers coughing jags

Stopped Smoking

- Loud nighttime wheezing ← **Gone**
- “Productive” morning cough ← **Gone**
- Laughing triggers coughing jags ← **Gone**



Smokers Who Can't Quit

- Institute of Medicine
 - 10 to 15% of adults will continue to smoke
 - 32.2 million to 46 million smokers
- Royal College of Physicians
 - Smokers smoke for nicotine
 - Substitutes could save millions of lives

Stratton, K., Shetty, P., Wallace, R., & Bondurant, S. (2001). Clearing the smoke: assessing the science base for tobacco harm reduction. Washington, DC: Institute of Medicine National Academies Press.

Tobacco Advisory Group of the Royal College of Physicians, October 2007. Harm reduction in nicotine addiction: Helping people who can't quit. ISBN 978-1-86016-319-7.



FDA CDER Misrepresentation

- Name calling – carcinogens & antifreeze
- Card-stacking (selective omission)
 - 8 ng/g TSNAs versus 126,000 ng/g
 - 1,000 cartridges/day might poison users
- Assertion – unsupported accusations
 - “could attract youth”
 - “could contain toxic ingredients”
- Bandwagon – many public health “experts” fear this product



Draft Report: Constituent Yields

- Nicotine yields similar to NRT
- Greatly reduced exposure to TSNAs
- Peer-reviewed literature omits vital data
- First rule of toxicology
 - The dose makes the poison
- Are heavy metals & chemicals at toxic levels?

Reduced TSNA Exposure

Product	Micrograms	Daily Dose	Daily Exposure
Nicotine patch – 4 mg	0.008 per patch	1 patch	0.008
*Electronic cigarette – 16 mg	0.00818 per g	1.5 g	0.012
Nicotine gum – 4 mg	0.002 per piece	8 pieces	0.016
Ariva orbs	0.19 per g	20 pieces (5.5 g)	1.045
Stonewall orbs	0.28 per g	20 pieces (5.5 g)	1.540
Skoal Bandits	1.3 per g	8 g	10.400
Swedish snus (General)	2.0 per g	8 g	16.000
Winston Full Flavor Cigarettes	3.4 per g	20 g (cigarettes)	68.000
Newport Full Flavor Cigarettes	3.9 per g	20 g (cigarettes)	78.000
Camel Full Flavor Cigarettes	5.2 per g	20 g (cigarettes)	104.000
Marlboro Full Flavor Cigarettes	6.3 per g	20 g (cigarettes)	126.000



Snus Effects on Smoking & Tobacco Use

	% Smoking	% Use Snus	% Use Tobacco
Sweden – Men 1981	34	13	47
Sweden – Men 2007	12	19	31
Sweden – Women 1981	26.7	0.3	27
Sweden – Women 2007	16	4	20

End Smoking NZ, Snuffing linked with lower overall cancer rates than smoking at the main sites of tobacco use.
<http://www.smokeless.org.nz/tobaccocancers.htm>

World Health Organization. 2008. Tobacco Control Database. Latest available figures: March 2008.
<http://data.euro.who.int/Default.aspx?TabID=2444> National statistic authorities

What if Everyone Used Nicotine?

		*Annual Deaths @ 90% less risk	Annual Deaths @ 99% less risk
2010 Total US Adult Population	312,394,000		
All Smokers Switch	45,300,000	39,268	3,927
All Non-users Start	267,094,000	231,530	23,153
Total Annual Deaths	442,083	270,799	27,080
Lives Saved per Year		171,284	415,003

*Levy DT, Mumford EA, Cummings KM, Gilpin EA, Giovino G, Hyland A, Sweanor D, Warner KE. The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: estimates of a panel of experts. Cancer Epidemiol Biomarkers Prev. 2004 Dec;13(12):2035-42.

Clearing the Smoke

“... the best way for those who already smoke to minimize their health risks is to **quit promptly**.”

Stratton, K., Shetty, P., Wallace, R., & Bondurant, S. (2001). Clearing the smoke: assessing the science base for tobacco harm reduction. Washington, DC: Institute of Medicine National Academies Press.

